REMARKS

The applicants have studied the final Office Action dated October 7, 2002, and respectfully request entry of this amendment under the provisions of 37 C.F.R. § 1.116(a) in that the amendment and remarks below place the application and the claims in condition for allowance and in better form for consideration on appeal. By virtue of this amendment, claims 35-55, 65-72 and 86-139 are pending, and claims 140-145 have been canceled without prejudice or disclaimer. Reconsideration and allowance of all of the claims in view of the above amendments and the following remarks are respectfully requested.

Remarks Regarding the Interview:

The applicants wish to thank the Examiner and her Primary Examiner for their time in the November 15, 2002 interview with the applicant's representatives. The discussions were helpful and are believed to have moved the case towards allowance. The applicants have canceled claims 140-145 and have provided the following remarks in accordance with the discussions with the Examiners.

In the hope of avoiding a further rejection, or an appeal, and to facilitate the Examiners' review, the applicants respectfully submit the following remarks and thoughts regarding the applicants perceptions and views of the Examiner's basis for rejecting the claims. Should the Examiner have any questions or would like to discuss any of the amendments or remarks, the Examiner is invited to call any of the undersigned representatives.

Remarks in Response to Rejections in the Outstanding October 7, 2002 Office Action:

To protect their rights in further applications or actions, the applicants must respectfully respond to and point out patentable differences between the claims, the cited art and the Examiner's detailed rejections and remarks made in the instant Office Action. The applicants will specifically point out where the applicants disagree with the Examiner's interpretation of the references. If the Examiner disagrees with the applicants remarks, the Examiner is requested to quote the language in the reference and to then specifically explain and point out why the

Examiner's position is correct. This is not being done to burden the Examiner. But must be done to avoid having applicants' silence on each of the Examiner's statements being treated as an admission.

Claims 140-145 were rejected under 35 U.S.C. § 112, second paragraph as being indefinite due to being dependent on canceled independent claim 73. Claims 140-145 have been canceled in accordance with the Examiner's remarks. Therefore, it is respectfully submitted that the rejection of claims 140-145 under 35 U.S.C. § 112, second paragraph, should be withdrawn.

Claims 51-55, 65, 67-69, 104-108 and 134-139 were rejected under 35 U.S.C. § 102(e) as being anticipated by Gross et al. 5,800,420. This rejection is respectfully traversed.

Embodiments of the present invention are directed to an external infusion device with a drive mechanism, a processor and an indication device. Moreover, the housing is sized to contain at least a portion of a reservoir within the housing. In addition, the drive mechanism is contained within the housing, and the drive mechanism operatively couples with the at least a portion of a reservoir within the housing. Also, the housing is sized to fit in a clothing pocket. In addition the embodiments recite different elements that distinguish the claims over the Gross et al. reference. The Gross et al. reference, either alone or in combination with any other references, does not disclose, teach or suggest a drive mechanism contained within the housing to couple with at least a portion of a reservoir in the housing, a device sized to fit in a clothing pocket, nor the additional elements recited in the claims.

The Gross et al. reference discloses a small infusion pump 10 that is combined with a needle 15 to infuse a medication, such as insulin, based upon the detected level of glucose from a sensor 22 present in the device 10. The rate of insulin infusion is adjusted by a signal from the sensor 22 that is input to the microprocessor of the device to control and maintain the glucose within desired ranges. Thus, the infusion pump 10 operates in a classical closed loop fashion utilizing a closed control loop to administer the medication, as discussed in the Gross et al. reference (see col. 1, lines 25-30 and col. 1, line 45 to col. 2, line 3).

However, due to the nature of the closed loop system used in the Gross et al. reference, the infusion pumps do not need to store additional parameters, since they would be superfluous or not needed. As disclosed in the Gross et al reference, a closed loop system that utilizes a sensor signal input to the microprocessor does not rely on programmed or stored protocols; rather only the sensor input is used to drive the infusion pump. On the other hand, the claimed infusion pumps can operate in an open loop mode and do not need to always utilize feedback from a sensor to operate. Although some versions of the claimed infusion pumps may also be used in a closed loop environment where such stored parameters might not be needed, the claimed infusion pumps still need these open loop capabilities to facilitate optimal infusion of medication, when the not utilized in closed-loop operations. Hence, they need stored parameters that allow the infusion pump to operate in predefined manners without the presence of closed loop feedback.

Claim 51 is distinguished over the Gross et al. reference by reciting "a processor coupled to the housing, a keypad coupled to the housing and used in conjunction with the processor to determine an estimate of remaining battery power, and an indication device to indicate the estimate of remaining battery power" (emphasis added). The Gross et al. reference does not disclose, teach or suggest the use of a keypad coupled to the housing of the infusion device to determine an estimate of remaining battery power. The Gross et al. device has no keypad – at best only a start button 63 (see col. 18, lines 48-50). The Gross et al. reference does not teach or suggest a device to estimate the remaining battery power, nor does it teach or suggest an indication device to indicate the estimate of the remaining battery power, as recited in claim 51. The Gross et al. reference does teach a threshold type low battery alarm when the battery is actually exhausted (see col. 19, lines 1-4), but this is not an estimate of the remaining battery power. Also, the key pad is not used in conjunction with the processor to determine the estimate of the remaining battery power.

Claims 52 and 53 are distinguished by reciting an "external infusion device comprising: ... a processor coupled to the housing, ...a memory coupled to and used in conjunction with the processor to store at least two personal delivery patterns, ... an indication device to indicate the

selected personal delivery pattern, wherein the processor controls the external infusion device in accordance with the selected one of the at least two personal delivery patterns" (emphasis added). The Gross et al. reference does not teach or suggest an external infusion device or a memory to store at least two personal delivery patterns, as recited in the claims. The Gross et al. reference operates in response to a glucose sensor signal and does not use parameters stored in memory to control the flow rate or pattern used by the patient (see col. 9, lines 19-23). The Examiner asserted that the Gross et al. reference teaches two personal delivery patterns. However, this is incorrect. The cited section at col. 1, lines 25-28 show only a single rate is used and the citation to col. 9, lines 19-23 shows only control using the sensor signal to set the rate. Thus, the Gross et al. reference does not teach or suggest a memory to store at least two personal delivery patterns, as recited in claims 52 and 53.

Claim 54 is distinguished by reciting an "external infusion device for infusion of a liquid into a body, the external infusion device comprising:...a memory coupled to and used in conjunction with the processor to store at least two basal rate profiles, a keypad coupled to the housing and used in conjunction with the processor to program the at least two basal rate profiles, and an indication device to indicate the basal rate profiles during programming, wherein the processor controls the external infusion device in accordance with the programmed at least two basal rate profiles" (emphasis added). The Gross et al. reference only describes and discloses using a glucose sensor to control the flow rate (see col. 9, lines 19-23). The Gross et al. reference does not disclose storing two basal rate profiles – at best the Gross et al. Background only shows one stored basal rate (see col. 1, lines 25-28). Thus, the Gross et al. reference does not disclose, teach or suggest an external infusion device including a memory to store at least two basal rate profiles, as recited in claim 54.

Claim 55 is distinguished by reciting an "external infusion device for infusion of a liquid into a body, the external infusion device comprising: a housing, a processor coupled to the housing, a memory coupled to and used in conjunction with the processor to store at least two bolus types, a keypad coupled to the housing and used in conjunction with the processor to select one of the at least two bolus types, and an indication device to indicate the selected bolus type,

wherein the processor controls the external infusion device in accordance with the selected one of the at least two bolus types" (emphasis added). The Gross et al. reference only describes and discloses using a glucose sensor to control the flow rate (see col. 9, lines 19-23). The Gross et al. reference does not disclose storing two bolus types – at best the Gross et al. Background only shows one stored bolus type (see col. 1, lines 25-28). Thus, the Gross et al. reference does not disclose, teach or suggest an external infusion device including a memory to store at least two bolus types, as recited in claim 55.

Claim 65 is distinguished from the Gross et al. reference by reciting "a vibration alarm used in conjunction with the processor to provide one or more tactile sensations to the user" (emphasis added). The Examiner has failed to cite any portion of the Gross et al. reference that discloses, teaches or suggests a vibration alarm to provide one or more tactile sensations to the user. The Gross et al. reference contains no description of a vibration device. The Gross et al. reference only describes an audio alarm, and the section cited by the Examiner only refers to "sounds" (see col. 18, line 21). In fact, the sections of the Gargano et al. reference cited by the Examiner make no mention of the use of vibrations, and does not teach or suggest the use of a vibration alarm, as recited in the claim 65.

Moreover, regarding claims 65 and 67-69, the Examiner asserted in the Office Action that an audio alarm is considered to be a vibration alarm (see page 4, first full paragraph of the instant Office Action). This is inconsistent with the customary usage of the term in various industries. Although both alarms utilize waves (sound or shaking), those of ordinary skill in the art clearly realize that a vibration alarm is not the equivalent of an audio alarm. The primary objective of one alarm is to provide a tactile sensation and the other is to provide a sound. For instance, although in a non-analogous field, manufacturers of pagers and cellular telephone consistently provide a vibration alert that is different from the audible ring. The user can select a particular one based on the environment they will be in. The Examiner has provided no reference or art that supports the argument that a vibration alarm is the same as an audio alarm. If the Examiner has such a reference, the Examiner should provide it and quote the relevant sections.

Claims 67-69, 104-108 and 134-139 depend from claims 51-55 and 65, which as discussed above is patentably distinguished over the Gross et al. reference. Therefore, dependent claims 67-69, 104-108 and 134-139 are also patentably distinguished over the Gross et al. reference for the same reasons.

Therefore, it is respectfully submitted that the rejection of claims 51-55, 65, 67-69, 104-108 and 134-139 under 35 U.S.C. § 102(e) by the Gross et al. reference should be withdrawn.

Claims 35-43, 70-72, 86-91, 104-133 and 140-145 were rejected under 35 U.S.C. § 103(a) as being unpatentable over by Gross et al. 5,800,420 in view of DeCant, Jr. et al. 4,443,218. This rejection is respectfully traversed.

As discussed above, claims 140-145 have been canceled. According the rejection of claims 140-145 is now moot. In addition, the remarks in this rejection regarding claims 58-64 are traversed, since these claims were canceled and allowed in another co-pending application.

As admitted by the Examiner, the Gross et al. reference does not disclose, teach or suggest any type of bolus estimator. The Gross et al. device uses a sensor signal and does not disclose the use of any information related to material to be ingested.

The DeCant, Jr. et al. reference does not make up for the deficiencies of the Gross et al. reference. The Examiner has cited no portion of the DeCant, Jr. et al. reference that in any manner teaches or suggests the embodiments recited in claims 35-43. For example, independent claim 35 recites an "external infusion device for infusion of a liquid into a body, the external infusion device comprising: ... a processor coupled to the housing, a bolus estimator used in conjunction with the processor and externally supplied values to estimate an amount of liquid to be infused based upon an estimate of a material to be ingested by the body; and an indication device to indicate when an amount of fluid to be infused has been calculated" (emphasis added). The DeCant, Jr. et al. reference does not disclose, teach or suggest an external infusion device that includes a bolus estimator used with a processor and external values to estimate an amount

of liquid to be infused based upon an estimate of a material to be ingested by the body. Thus, the DeCant, Jr. et al. reference does not disclose, teach or suggest a bolus estimator that provides an estimate of ingested material, as recited in claim 35.

The DeCant, Jr. et al. reference discloses and implantable pump with the ability to switch between two delivery rates. The DeCant, Jr. et al. reference does describe that the patient can tailor the bolus rate to match the characteristics of the meal, as shown at col. 2, lines 39-42. However, it is clear from the description (see col. 5, lines 55-59 and col. 8, lines 47-48 and 53-63) that the bolus delivery is accomplished solely in response to the use of a switch 96, or a limited patient programmer, that lets the patient only switch between a basal flow rate and a higher bolus flow rate (see col. 8, line 64 to col. 9, line 17). Thus, the patient must manually switch or command the implantable pump to change flow rates to deliver a desired bolus amount. There is no disclosure, teaching or suggestion anywhere in the DeCant, Jr. et al. reference of the implantable pump actually calculating the duration of or the size of the bolus delivery. It is all up to the patient to determine by approximation or determination without the aid of any feature contained in the implantable pump. Also, there is no disclosure, teaching or suggestion of the implantable pump providing an estimate or how an estimate from an internal implantable infusion pump could be made available to a user.

Conversely, the claimed bolus estimator uses the processor (either as part of the processor or as a separate element) and externally supplied values to estimate the amount of liquid to be infused. Thus, the patient need not guess how much fluid is needed, the external infusion device performs the calculation and provides that information to the patient. Therefore, the teaching of DeCant, Jr. et al. implantable pump is fundamentally different, since it requires the patient to determine when to start and end the bolus rate, while the claimed bolus estimator determines an estimate based on various values supplied to the external infusion device and informs the patient of an estimate of an amount of fluid to be infused.

During the discussions in the various interviews, the Examiner stated the bolus estimator is essentially a calculator and that any processor could do the calculations. The applicants do not

assert that a calculator or a processor could not do calculations similar to the bolus estimator. However, the Examiner has not cited a single patent reference that includes the bolus estimator within the infusion device in combination with the other elements of the infusion device. In addition, the Examiner has not cited a single reference where the user inputs values representing an amount of material to be ingested and then the estimator uses that value to come up with an estimate of an amount of fluid to be infused to compensate for the amount of material ingested fluid. The Examiner has also not shown any calculator or processor reference that also includes some teaching or suggestion to modify the calculator or processor to be included in an infusion device or the desirability to do so.

Moreover, it is respectfully submitted that it would not have been obvious to combine the Gross et al. and De Cant, Jr. et al. references, as suggested by the Examiner. It is well settled that a reference must provide some motivation or reason for one skilled in the art (working without the benefit of the applicants' specification) to make the necessary changes in the disclosed device. The mere fact that a reference may be modified in the direction of the claimed invention does not make the modification obvious unless the reference expressly or impliedly teaches or suggests the desirability of the modification. In re Gordon, 221 USPQ 1125, 1127 (Fed. Cir. 1984); Ex parte Clapp, 227 USPQ 972, 973 (Bd. App. 1985); Ex parte Chicago Rawhide Mfg. Co., 223 USPQ 351, 353 (Bd. App. 1984).

The cited references, Gross et al. and De Cant, Jr. et al., fail to meet the basic requirement for a finding of obviousness established by the courts in Gordon, Clapp, and Chicago Rawhide. There is no suggestion in any of the references of modifying the devices disclosed therein in the direction of the present invention, nor is there any suggestion whatsoever of the desirability of such modification (i.e., of a taking a closed loop external system that uses sensor signal to control the infusion pump and combining it with an implantable pump that can switch between a basal rate and a bolus rate to yield an external infusion device including a bolus estimator that uses the input of material to be ingested to determine an estimate of the amount of liquid to be infused). Thus, it is respectfully submitted that the ordinarily skilled artisan would have no motivation to combine the references as suggested by the Examiner.

Claims 36-43, 70-72, 86-91, 104-133 and 140-145 depend from claims 35 and 52, which as discussed above are patentably distinguished over the Gross et al. and DeCant, Jr. et al. references. Therefore, claims 36-43, 70-72, 86-91, 104-133 and 140-145 are also patentably distinguished over the Gross et al. and DeCant, Jr. et al. references for the same reasons.

Claims 36, 37, and 40 are further distinguished from the Gross et al. and DeCant, Jr. et al references by reciting specific additional features of the bolus estimator that are not disclosed, taught, or suggested in the DeCant, Jr. et al. reference. The Examiner has cited, no portion of the DeCant, Jr. et al. reference that teaches or suggests an external infusion device with a bolus estimator that includes "the capability to calculate a correction bolus based upon a current characteristic value and a target characteristic value," as recited in claim 36, or "a liquid sensitivity that is used to determine the amount of liquid to be infused to calculate the correction bolus," as recited in claim 37, or "a lockout to prevent the calculation of a bolus for a predetermined period of time after a bolus is estimated by the bolus estimator," as recited in claim 40. The Examiner makes broad statements that these elements are disclosed in the DeCant, Jr. et al. reference, but this is simply not the case and the sections specifically cited by the Examiner do not contain any language that could be construed to cover these elements. If the Examiner believes that these elements are described in the DeCant, Jr. et al. reference, the Examiner should quote the specific language that supports, shows and meets the limitations in the claims. The applicants respectfully submit that this is simply not possible.

Claims 38 and 39 are further distinguished over the Gross et al. and DeCant, Jr. et al. references by reciting "the liquid to be infused is insulin" and "where the material to be ingested is carbohydrates," respectively. While the DeCant, Jr. et al. implantable pump may be used for insulin pumps, there is no teaching or suggestion in the DeCant, Jr. et al. reference of the additional feature of a device to estimate an amount of insulin to be infused based upon an estimate of carbohydrates to be ingested by the body, as recited in claims 38 and 39.

Claims 41 and 42 are further distinguished over the Gross et al. and DeCant, Jr. et al.

references by reciting that the supplied values used in conjunction with the a bolus estimator and the processor are "codes representing a carbohydrate value of specific foods" or "codes representing a carbohydrate value of specific meals," respectively. The DeCant, Jr. et al. reference does not teach or suggest the additional feature of a device with a bolus estimator that accepts codes representing a carbohydrate value of foods or meals, as recited in claims 41 and 42.

Claim 43 is further distinguished over the Gross et al. and DeCant, Jr. et al. references by reciting that the external infusion device further includes "a duration factor to determine a value of how long a previously infused amount of liquid will remain active in the body, wherein the determined value is used to adjust the amount of the fluid to be infused" (emphasis added). Thus, the Examiner has cited no portion of the DeCant, Jr. et al. reference that teaches or suggests the additional feature of a duration factor to adjust the amount of the fluid to be infused.

Claim 70 is further distinguished by reciting an external infusion device including a processor to store at least two personal delivery patterns "wherein the at least two personal delivery patterns are programmable by a user," (emphasis added). As discussed previously, the Gross et al. and DeCant, Jr. et al. references do not teach or suggest a memory to store at least two personal delivery patterns, as recited in the claims. The Gross et al. and DeCant, Jr. et al. references do not teach or suggest a memory to store at least two personal delivery patterns, as recited in the claims. Thus, values for only one set of parameters are stored for the single flow rate pattern used by the patient, and the Gross et al. and DeCant, Jr. et al. references do not teach or suggest a memory to store at least two personal delivery patterns, as recited in claim 70.

Claims 71 and 72 are further distinguished over the Gross et al. and DeCant, Jr. et al. references, by virtue of arguments presented earlier that the Gross et al. and DeCant, Jr. et al. references, do not teach or suggest the use of two or more personal delivery patterns. Claims 71 and 72 serve to further define embodiments of the present invention. The applicants respectfully submit that claims 71 and 72 do not read on the Gross et al. and DeCant, Jr. et al. references and are in condition for allowance.

Therefore, it is respectfully submitted that the rejection of claims 35-43, 70-72, 86-91, 104-133 and 140-145 under 35 U.S.C. § 103(a) by the Gross et al. reference in view of DeCant, Jr. et al. reference should be withdrawn.

Claim 66 was rejected under 35 U.S.C. §103(a) over Gross et al. 5,800,420 in view of Gargano et al. 5,814,015. This rejection is respectfully traversed.

Claim 66 depends from claim 65, which as discussed above is patentably distinguished over the Gross et al. reference. Therefore, claim 66 is also patentably distinguished over the Gross et al. reference for the same reasons.

The Gargano et al. reference does not make up for the deficiencies of the Gross et al. reference. The Examiner has failed to cite any portion of the Gargano et al. reference that discloses, teaches or suggests a vibration alarm to provide one or more tactile sensations to the user. The Gargano et al. reference contains no description of a vibration device. In fact, the sections of the Gargano et al. reference cited by the Examiner make no mention of the use of vibrations, and does not teach or suggest the use of a vibration alarm, as recited in the claim 66. In addition, it is noted that a vibration alarm on a hospital pump that sits on an independent and free-standing IV pole is unlikely to be effective.

Therefore, it is respectfully submitted that the rejection of claim 66 under 35 U.S.C. § 103(a) by the Gross et al. reference in view of Gargano, Jr. et al. reference should be withdrawn.

Claims 44-50 and 92-103 were rejected under 35 U.S.C. § 103(a) as being unpatentable over by Gross et al. 5,800,420 in view of Dent, 5,609,060. This rejection is respectfully traversed.

Claims 44-50 are further distinguished over the Gross et al. reference by claiming unique applications or uses for the vibration alarm. Claims 44-46 state that the vibration alarm is used to, "remove gas bubbles from the fluid in the reservoir during priming," "agitate fluid in the

reservoir between successive delivery periods," or "agitate the fluid in the reservoir during delivery," respectively. Claims 48 and 49 recite similar language. Claim 47 recites, " a vibration alarm used in conjunction with the processor and the audible alarm." And claim 50 recites that, "the processor selects to activate one of the audible alarm and vibration alarm independently." The Gross et al. reference does not disclose, teach, or suggest uses for a vibration alarm alone, or in conjunction with an audible alarm, as recited in claims 44-50.

The Dent reference does not make up for the deficiencies of the Gargano et al. reference. The Dent reference is directed to a multiple channel manometer apparatus to provide information regarding the function of the digestive tract in animals and children. The device uses water and carbon dioxide, and flushes the channels using gas. There is no disclosure of a vibrator to remove bubbles. Rather, a user carefully vibrates (or shakes) the lines and connectors (see col. 2, lines 32-36). In addition, there is no disclosure of using an alarm vibrator to also remove the bubbles, as recited in the claims.

Claims 92-103 depend from claims 44 and 47, which as discussed above are patentably distinguished over the Gross et al. and Dent references. Therefore, claims 92-103 are also patentably distinguished over the Gross et al. and Dent references for the same reasons.

Therefore, it is respectfully submitted that the rejection of claims 44-50 and 92-103 under 35 U.S.C. § 103(a) by the Gross et al. reference and the Dent reference should be withdrawn.

The applicants have reviewed the Worthington et al. 5,822,715 reference made of record and not relied upon. The applicants note that the Worthington et al. reference only discloses suggesting a new insulin correction based on current glucose values and previous insulin injections. It does not disclose, teach or suggest "a bolus estimator used in conjunction with the processor and externally supplied values to estimate an amount of liquid to be infused based upon an estimate of a material to be ingested by the body" (emphasis added), as recited in claims 35-43 and 87-91.

In view of the foregoing, it is respectfully submitted that the application and all of the claims are in condition for allowance. Reexamination and reconsideration of the application, as amended, are requested.

If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is invited to call the undersigned attorney at (818) 576-5313 should the Examiner believe a telephone interview would advance the prosecution of the application.

Respectfully submitted,

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